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# Quality of British and American Nationwide Quality of Care and Patient Safety Benchmarking Programs: Case Neurosurgery

Elina Reponen, MD, PhD\*  
Hanna Tuominen, MD, PhD\*  
Miikka Korja, MD, PhD\*

\*Department of Anesthesiology, Intensive Care and Pain Medicine, University of Helsinki and Helsinki University Hospital, Helsinki, Finland;  
\*Department of Neurosurgery, University of Helsinki and Helsinki University Hospital, Helsinki, Finland

## Correspondence:

Elina Reponen, MD, PhD,  
PO Box 900,  
00029 HUS, Finland.  
Email: [elina.reponen@hus.fi](mailto:elina.reponen@hus.fi)

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**BACKGROUND:** Multiple nationwide outcome registries are utilized for quality benchmarking between institutions and individual surgeons.

**OBJECTIVE:** To evaluate whether nationwide quality of care programs in the United Kingdom and United States can measure differences in neurosurgical quality.

**METHODS:** This prospective observational study comprised 418 consecutive adult patients undergoing elective craniotomy at Helsinki University Hospital between December 7, 2011 and December 31, 2012. We recorded outcome event rates and categorized them according to British Neurosurgical National Audit Programme (NNAP), American National Surgical Quality Improvement Program (NSQIP), and American National Neurosurgery Quality and Outcomes Database (N<sup>2</sup>QOD) to assess the applicability of these programs for quality benchmarking and estimated sample sizes required for reliable quality comparisons.

**RESULTS:** The rate of in-hospital major and minor morbidity was 18.7% and 38.0%, respectively, and 30-d mortality rate was 2.4%. The NSQIP criteria identified 96.2% of major but only 38.4% of minor complications. N<sup>2</sup>QOD performed better, but almost one-fourth (23.2%) of all patients with adverse outcomes, mostly minor, went unnoticed. For NNAP, a sample size of over 4200 patients per surgeon is required to detect a 50.0% increase in mortality rates between surgeons. The sample size required for reliable comparisons between the rates of complications exceeds 600 patients per center per year.

**CONCLUSION:** The implemented benchmarking programs in the United Kingdom and United States fail to identify a considerable number of complications in a high-volume center. Health care policy makers should be cautious as outcome comparisons between most centers and individual surgeons are questionable if based on the programs.

**KEY WORDS:** Quality of care, Patient safety, Benchmarking

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Patient safety measures together with transparent outcome reporting have recently become a major focus of interest in medicine. Particularly among surgical communities, such interest is understandable, as up

to 50% of hospital errors can be traced back to operating theaters, and more than a half of the errors may contribute to the development of complications.<sup>1,2</sup> The increasing interest in conducting systematic approaches to measure surgical outcomes has led to the situation where a number of nationwide complication and outcome registries have been implemented, and these registries are exploited to compare patient safety and quality of care figures between institutions, and even between surgeons.

In neurosurgery, the Society of British Neurological Surgeons launched in April 2014 the Neurosurgical National Audit Programme (NNAP), which has been mandated to publish nationwide and transparent (open-access) 30-d (from the date of admission) mortality

**ABBREVIATIONS:** ACS, American College of Surgeons; AMI, acute myocardial infarction; DVT, deep venous thromboembolism; NNAP, Neurosurgical National Audit Programme; NSQIP, National Surgical Quality Improvement Program; N<sup>2</sup>QOD, National Neurosurgery Quality and Outcomes Database; OR, operating room; PE, pulmonary embolism; PROMs, patient-reported outcome measures; RR, relative risk; UTI, urinary tract infection

rates stratified by neurosurgeons and surgical units. The nationally validated but voluntary quality improvement project in the United States, the American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP), was introduced in 1999. By joining the program, hospitals can voluntarily report surgical results (outcome within 30 postoperative days) on an open-access website. The NSQIP is a popular source of big data for exploring national trends and outcomes in neurosurgery,<sup>3-7</sup> including cranial neurosurgery.<sup>8-16</sup> The NSQIP data have been criticized for systemic inaccuracies and lack of validity in neurosurgery outcomes research, however.<sup>17</sup> The American Association of Neurological Surgeons has launched a Cerebrovascular Module of the National Neurosurgery Quality and Outcomes Database (N<sup>2</sup>QOD) in December 2014. The database serves as a national but voluntary registry, and its primary goal is to prospectively assess and report quality of neurosurgical care,<sup>18</sup> with emphasis on clinically meaningful data for neurosurgeons.<sup>19</sup> Generally, developing reliable quality registers is welcome: patient satisfaction, a poor proxy for quality of care and postoperative morbidity,<sup>20</sup> has emerged as a popular metric for quality of care in a variety of uses ranging from hospital reimbursement in the United States<sup>21</sup> to public internet-based comparisons between treatment centers in Australia.<sup>22</sup>

We aimed to evaluate how accurately the used outcome variables in these quality programs reflect complication rates after elective cranial neurosurgery in a high-volume academic center, and whether the programs serve their purpose in quality of care comparisons in major surgery.

## METHODS

### Ethics Statement

The Ethics Committee of the Hospital District of Helsinki and Uusimaa reviewed and approved this study (DNRO 127/13/03/02/2011). We followed the principles of the World Medical Association's Declaration of Helsinki 2013 revision. All subjects gave a written informed consent before data collection.

### Study Area

In Finland, all intracranial neurosurgical operations are performed in one of the five public university hospitals, of which Helsinki University Hospital is the largest with a catchment area of nearly 2 million people. Helsinki University Hospital is a large hospital organization with 21 hospitals, over 22 000 employees and over 100 000 annual surgical procedures. The total population in Finland at the end of 2012 was 5 426 674 people.

### Patient Cohort and Data Collection

The patient cohort, data collection methods, and enrollment protocol have been described in detail previously.<sup>20,23,24</sup> In brief, a consecutive series of 418 adult ( $\geq 18$  yr) patients, who underwent elective craniotomies between December 7, 2011 and December 31, 2012 in the Department of Neurosurgery, (<http://www.hus.fi/en/medical-care/medical-services/Neurosurgery>) of Helsinki University Hospital (<http://www.hus.fi/en>), were enrolled at the time of the first craniotomy.

Prospective data collection persisted until death or for 30 d, whichever came first. We conducted a structured follow-up telephone interview at 30 d to evaluate postoperative outcome and functional status. The study had no impact on the standard in-hospital treatment and care.

### Recorded Outcomes

Outcome measures included in-hospital mortality, 30-d mortality, and in-hospital morbidity as defined previously.<sup>20,24</sup> In this study, major morbidity included 30-d postoperative mortality, deep venous thromboembolism (DVT), pulmonary embolism (PE), acute myocardial infarction (AMI), pneumonia, sepsis, a new or worsened hemiparesis or radiological stroke (transient or permanent), and unplanned re-craniotomies or endovascular interventions. Minor postoperative morbidities included new or worsened facial nerve palsy, meningitis/wound infection, minor infections such as urinary tract infection (UTI), visual impairment (also subjective), dysphasia/dysarthria, dysphagia, and minor cranial reoperations in the operating room (OR). Overall morbidity comprised both major and minor morbidity.

### Outcome Measures in Nationwide Big Data Registries

The sole outcome measure reported in the British NNAP is 30-d (from the date of surgery) mortality (Table 1). The NSQIP program in the United States collects data on 136 variables, of which at least 20 are suitable as 30-d outcome measures in cranial neurosurgery (Table 1). These variables are surgical site infection (superficial, deep, and organ), wound disruption, pneumonia, unplanned reintubation, PE, ventilator  $>48$  h, progressive renal insufficiency, acute renal failure, UTI, peripheral nerve injury, stroke/cerebrovascular attack with neurological deficit, coma  $>24$  h, cardiac arrest requiring CPR, myocardial infarction, graft/prosthesis/flap failure, bleeding transfusions, DVT/thrombophlebitis, sepsis, septic shock, and return to operation room (OR; Table 1). Both the NNAP and the NSQIP are administrative registries. The cerebrovascular module of the N<sup>2</sup>QOD has been introduced by the American Association of Neurological Surgeons, and includes 19 outcome variables in total (Table 1). Of these, 10 variables are recorded before hospital discharge (neurological events, respiratory events, cardiac events, renal events, hepatic dysfunction during the hospitalization, infectious disease events, hypercoagulation events, metabolic events, other events, and unplanned return to OR during hospitalization) and 5 post discharge up to 30 postoperative days (readmission to hospital within 30 d of surgery, return to OR within 30 d of surgery, patient died within 30 d of surgery). Additionally, modified Rankin Scale and global health scale are recorded both at 6-mo and at 12-mo follow-up (optional). The N<sup>2</sup>QOD is a clinically oriented registry.

### Statistical Methods

We described the rates of individual complications and composite outcome measures (major and minor morbidity) as well as 30-d mortality in our prospective cohort. To estimate sample sizes needed to reliably compare two proportions (complication rates) we used a 2-sample, 2-sided equality test based on the following hypotheses:

$$H_0 : p_A - p_B = 0, H_1 : p_A - p_B \neq 0$$

Where  $p_A$  is the proportion in group A and  $p_B$  in group B. We assumed equal sample sizes:

$$\kappa = \frac{\eta_A}{\eta_B} = 1$$

**TABLE 1. Outcome Events in National Quality Registers and 1-yr Prospective Cohort. An “I” Indicates the Outcome Event is Included in Each Individual Register. Outcome Events Marked With an “X” are not Included in the Register**

	Prospective	NSQIP	N <sup>2</sup> QOD	NNAP
SSI	I	I	Infectious disease event	X
Sepsis	I	I	Infections disease event	X
Septic shock		I	Infections disease event	X
Urinary tract infection	I	I	Infections disease event	X
Pneumonia <sup>a</sup>	I	I	Infections disease event	X
Unplanned reintubation	X	I	Respiratory event	X
Ventilator > 48 h	X	I	Respiratory event	X
Progressive renal insufficiency	X	I	Renal event	X
Acute renal failure	X	I	Renal event	X
Cardiac arrest requiring CPR	I	I	Cardiac event	X
Myocardial infarction		I	Cardiac event	X
Pulmonary embolism	I	I	Hypercoagulation event	X
DVT/thrombophlebitis	I	I	Hypercoagulation event	X
Stroke/CVA with neurological deficit	I	I	Neurological event	X
Facial nerve palsy/peripheral nerve injury	I	I	Neurological event	X
Dysphasia/dysarthria	I	X	Neurological event	X
Dysphagia	I	X	Neurological event	X
Visual impairment	I	X	X	X
Return to OR during hospitalization	I	I	I	X
Return to OR within 30 d	I	I	I	X
Wound disruption	X	I	X	X
Coma > 24 h	X	I	X	X
Bleeding requiring transfusions	X	I	X	X
graft/prosthesis/flap failure	X	I	X	X
Metabolic events	X	X	I	X
Other events	X	X	I	X
Hepatic dysfunction during hospitalization	X	X	I	X
Re-admit to hospital within 30 d	X	X	I	X
Silent stroke	I	X	X	X
In-hospital mortality	I	X	X	X
30-d mortality	I	I	I	I

Abbreviations: CPR, cardiopulmonary resuscitation; CVA, cerebrovascular attack; DVT, deep venous thromboembolism; NNAP, National Neurosurgery Audit Programme; N<sup>2</sup>QOD, National Neurosurgery Quality and Outcomes Database; NSQIP, National Surgical Quality Improvement Program; OR, operating room; SSI, surgical site infection.

<sup>a</sup>Also included in respiratory events.

We then used the following formulas to calculate sample sizes:

$$\eta A = \eta B,$$

$$\eta A = \left\{ z_{1-\alpha/2} \times \sqrt{\bar{p} \times \bar{q} \times \left(1 + \frac{1}{k}\right)} + z_{1-\beta} \times \sqrt{p_A \times q_A + \left(\frac{p_B \times q_B}{k}\right)} \right\}^2 / \Delta^2$$

$$q_A = 1 - p_A$$

$$q_B = 1 - p_B$$

$$\bar{p} = \frac{p_A + k p_B}{1 + K}$$

$$\bar{q} = 1 - \bar{p}$$

where  $z_{\alpha/2}$  is the critical value of the normal distribution at  $\alpha/2$  and  $z_{\beta}$  is the critical value of the normal distribution at  $\beta$ . Additionally, we estimated sample sizes for a relative risk (RR) of 2 with a 2-sided test suitable for unmatched case/control studies using the same hypotheses and assumptions as described above. The previously presented formula with the following assumptions served for the calculations:

$$p_B = p_A \times RR / (1 + p_A \times (RR - 1))$$

## RESULTS

### Patient Characteristics and Surgeries

The patient characteristics of the 418 study patients are presented in Table 2. The age of the 418 patients varied between 18 and 87 yr, and more than half (62%) were women. The age was  $\leq 40$  yr in 14% of the patients, and  $\geq 70$  yr in 16%. Only 13 (3%) patients were 80 yr old or older. Vascular lesions, benign

**TABLE 2. Basic Demographic and Surgery-Related Factors for 418 Consecutive Elective Craniotomy Patients Categorized by the Type of the Lesion**

Variables	Patients n = 418
<b>Age (years)</b>	
Mean (range)	56.4 (18-87)
Median	58.0
<b>Sex n (%)</b>	
Female	260 (62.2)
Male	158 (37.8)
In-hospital mortality n (%)	4 (1.0%)
30-d mortality n (%)	10 (2.4%)

tumors, and malignant tumors accounted for more than 90% of surgeries.

### Outcome Events in Prospective Cohort

The in-hospital and 30-d mortality rates were low (Table 2). Almost one-half (46.4%) of the patients had at least one recorded major or minor complication. The rates of overall, major, and minor morbidity are presented in Table 3. The detailed numbers of individual postoperative major and minor complications in different indication groups are summarized in Table 4. The percentage of patients with overall, major, and minor morbidity in the prospective cohort identified by the reporting criteria of NNAP, NSQIP, and N<sup>2</sup>QOD are depicted in Figure. All but one of the 10 patients who died within 30 postoperative days had at least one recorded complication. The most frequent complications reported among the deceased patients were pneumonia (3 patients), hemiparesis or a radiological stroke (3 patients), and AMI (2 patients).

### Outcome Events According to NNAP

The only outcome event reported in the NNAP is 30-d mortality. Presuming the recorded 30-d mortality rate of 2.4% in our prospective cohort, detecting a statistically significant

( $\alpha = 0.05$ , power 0.9) 50% increase in 30-d mortality between two surgeons would require a sample size of 4245 patients per surgeon or per center. Thus, assuming statistical significance is defined as  $P \leq .05$ , the mortality difference of 10 vs 15 patients could be explained by chance variation if sample size is less than 4245 in a nontime-dependent analysis.

### Outcome Events According to NSQIP

The NSQIP criteria identified 96.2% of major morbidity but only 38.4% of minor morbidity in our prospective cohort (Figure). All patients with new or worsened hemiparesis, the most common individual major morbidity (9.8%) in our cohort, were identified according to NSQIP criteria.

Using the NSQIP program, detecting a statistically significant difference ( $\alpha = 0.05$ , power 0.9) between one treatment center with a hemiparesis rate of 5% and another of 10% would require a sample size of 582 patients from each center or each surgeon (Table 5). If estimating differences between other individual major complications, which were more infrequent, even larger sample sizes are necessary (Table 5). If using a composite outcome measure (for example, the rate of major complications in our cohort was 18.7%) instead of single NSQIP criteria, detecting a statistically significant ( $\alpha = 0.05$ , power 0.9) difference between two centers with major complication rates of 10% and 20% would require a sample size of 266 patients from each center.

### Outcome Events According to N<sup>2</sup>QOD

Altogether, 149 (76.8%) patients with major or minor complications in our cohort were identifiable by N<sup>2</sup>QOD criteria. Separate analyses for individual complications are not feasible as N<sup>2</sup>QOD uses composite outcome events. The N<sup>2</sup>QOD composite events identified 96.2% of major morbidity and 70.4% of minor morbidity reported in our prospective cohort (Figure).

According to N<sup>2</sup>QOD criteria, the overall morbidity rate in our cohort was only 35.6%; almost a fourth (23.2%) of all patients with complications (35.6% vs 46.4%) went unnoticed. To detect a statistically significant ( $\alpha = 0.05$ , power 0.9) difference between two centers with complication rates of 36% and 46%, the

**TABLE 3. Summary of the Frequency of Major Morbidity, Minor Morbidity, and Overall Morbidity in Patients Categorized by Indication for Craniotomy and age Dichotomized at  $\geq 64$  yr. Both Outcomes Comprise Patients With 1 or Multiple Complications. In Case Both Major and Minor Complications Were Identified, the Individual is Included in Each Category**

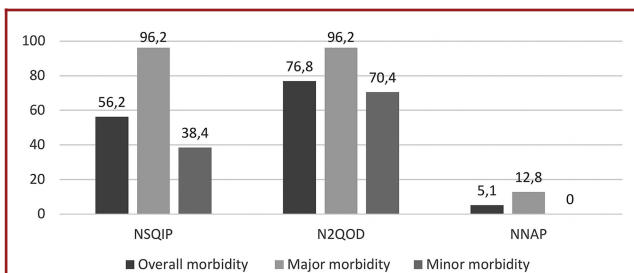
Patients	Major morbidity patients (%)	Minor morbidity patients (%)	Overall morbidity patients (%)
All (n = 418)	78 (18.7)	159 (38.0)	194 (46.4)
Age $\geq 64$ (n = 138)	38 (27.5)	53 (38.4)	73 (52.9)
Vascular (n = 138)	15 (10.9)	56 (40.6)	62 (44.9)
Age $\geq 64$ (n = 33)	7 (21.2)	20 (60.6)	22 (66.7)
Benign (n = 135)	29 (21.5)	58 (43.0)	69 (51.1)
Age $\geq 64$ (n = 49)	15 (30.6)	17 (34.7)	25 (51.0)
Malignant (n = 121)	31 (25.6)	38 (31.4)	55 (45.5)
Age $\geq 64$ (n = 49)	16 (32.7)	14 (28.6)	24 (49.0)



**TABLE 4. Rates of Recorded Postoperative Complications by Indication**

Complication	All (n = 418) n (%)	Vascular lesion (n = 138) n (%)	Benign tumor (n = 135) n (%)	Malignant tumor (n = 121) n (%)	Other (n = 24) n (%)
New or worsened hemiparesis	41 (9.8)	10 (7.2)	14 (10.4)	17 (14.0)	0 (0.0)
Silent stroke	6 (1.4)	1 (0.7)	3 (2.2)	2 (1.7)	0 (0.0)
Deep venous thromboembolism	2 (0.5)	0 (0.0)	0 (0.0)	2 (1.7)	0 (0.0)
Pulmonary embolism	3 (0.7)	0 (0.0)	1 (0.7)	2 (1.7)	0 (0.0)
Acute myocardial infarction	4 (1.0)	0 (0.0)	3 (2.2)	1 (0.8)	0 (0.0)
Pneumonia	14 (3.3)	6 (4.3)	4 (3.0)	4 (3.3)	0 (0.0)
Unplanned re-craniotomy or endovascular intervention <sup>a</sup>	17 (4.1)	1 (0.7)	8 (5.9)	7 (5.8)	1 (4.2)
Wound infection, meningitis	9 (2.2)	4 (2.9)	3 (2.2)	2 (1.7)	0 (0.0)
Minor infections (for example urinary tract infection)	39 (9.3)	17 (12.3)	9 (6.7)	8 (6.6)	5 (20.8)
Postoperative visual impairment	76 (18.2)	33 (23.9)	24 (17.8)	16 (13.2)	3 (12.5)
New or worsened facial nerve Palsy	14 (3.3)	0 (0.0)	8 (5.9)	6 (5.0)	0 (0.0)
Dysphasia, dysarthria	49 (11.7)	12 (8.7)	19 (14.1)	18 (14.9)	0 (0.0)
Dysphagia	26 (6.2)	10 (7.2)	12 (8.9)	4 (3.3)	0 (0.0)
Unplanned minor cranial reoperations in the operating room <sup>a</sup>	3 (0.7)	0 (0.0)	3 (2.2)	0 (0.0)	0 (0.0)

<sup>a</sup>Overall, 19 (4.5%) patients had an unplanned reoperation involving the head during the 30-d follow-up, 12 (2.9%) patients before discharge and an additional 7 (2.2%) patients during days 7 to 30 after the first surgery. Of all reoperated patients, 16 underwent a re-craniotomy, 1 patient twice. Of the 2 patients who had a ventriculostomy, one underwent a subsequent re-craniotomy. Two patients had a cerebrospinal fluid fistula repaired, 1 patient coiling of an intracranial aneurysm, and 1 patient had surgical wound revision. The reoperations resulted in further complications in 5 patients (26.3% of the reoperations).



**FIGURE.** The accuracy (%) of nationwide neurosurgical quality programs in detecting postoperative overall, major and minor morbidity compared to prospective complications data in elective cranial neurosurgery in Helsinki University Hospital. Abbreviations: NNAP, Neurosurgical National Audit Programme; N2QOD, National Neurosurgery Quality and Outcomes Database; NSQIP, American College of Surgeons National Surgical Quality Improvement Program.

required sample size would be 416 patients from each center, a number only feasible in the largest neurosurgical centers.

## DISCUSSION

The annual number of elective craniotomies in a majority of neurosurgical units rarely exceeds 600, a number required to statistically detect a significant difference in the incidence of the most common complication—new or worsened hemiparesis—between two centers. Composite outcome measures may serve the purpose to satisfy the power requirement for detecting significant differences between centers surveyed in large national registries.

Despite being important pioneers in patient safety and quality of care improvement, however, results from these registers should be interpreted with caution, especially since contributing data is voluntary and systemic data inaccuracies have been observed.<sup>17</sup> By 2017, it is estimated that about 9% of Medicare payments to hospitals will be based on reporting and performance of quality metrics,<sup>25</sup> implicating a strong financial incentive behind participating in these programs. Particularly surgeon-specific outcome reporting of rare complications such as mortality from the registries seems inadequate in major surgery, such as neurosurgery.

The strengths of our study include the prospective study design, consecutive and unselected cohort of patients, high-volume academic center (minimal selection bias), and multiple surgeons (increased external validity). Cumulative sums of individual complications can only be reported from prospective cohorts. The study also has weaknesses. First, the cohort size of 418 patients is relatively small, despite the fact that the study was conducted in a high-volume neurosurgical unit. It should be noted, however, that in large register-based studies, the caseloads of individual participating hospitals are often much lower. Furthermore, the studied outcome programs are meant for a clinical use in neurosurgical units, most of which have smaller caseloads than the study hospital. Large-scale multicenter or even multinational studies are needed to confirm our findings and their generalizability. Despite rigorous efforts to record all postoperative complications reported both by physicians and by patients themselves, it is possible that some complications went unidentified. To improve the data collection, neurosurgical units should routinely record patient-reported complications data and

**TABLE 5. Sample Size Calculations for Detecting a Statistically Significant Difference in the Hypothetically Doubled Complication Rates Between 2 Surgeons**

		Complication rates					
Surgeon A	0.5%	1.0%	2.0%	5.0%	10.0%	20.0%	30.0%
Surgeon B	1.0%	2.0%	4.0%	10.0%	20.0%	40.0%	60.0%
<b>2-sample, 2-sided equality</b>							
<b>N per surgeon</b>							
power (1- $\beta$ ) = 0.8, $\alpha$ = 0.05	4673	2319	1141	435	199	82	42
power (1- $\beta$ ) = 0.9, $\alpha$ = 0.05	6256	3103	1527	582	266	109	56
<b>N total</b>							
power (1- $\beta$ ) = 0.8, $\alpha$ = 0.05	9346	4638	2282	870	398	164	84
power (1- $\beta$ ) = 0.9, $\alpha$ = 0.05	12 512	6206	3054	1164	532	218	112
<b>Risk ratio = 2</b>							
<b>N per surgeon</b>							
power (1- $\beta$ ) = 0.8, $\alpha$ = 0.05	4752	2398	1221	516	283	172	141
power (1- $\beta$ ) = 0.9, $\alpha$ = 0.05	6361	3209	1634	690	378	230	188
<b>N total</b>							
power (1- $\beta$ ) = 0.8, $\alpha$ = 0.05	9504	4796	2442	1032	566	344	282
power (1- $\beta$ ) = 0.9, $\alpha$ = 0.05	12 722	6418	3268	1380	756	460	376

Abbreviations:  $\alpha$ , type I error;  $\beta$ , type II error; N, Number of patients.

strive for the efficient utilization of structured data available in electronic patient records.

According to our results, in-hospital and 30-d mortality rates in modern neurosurgery are so low, that mortality is inadequate as a sole measure in outcome comparisons. In our hospital, a 30-d mortality rate per neurosurgeon is one event every second year on average. The required sample size for detecting true differences between two surgeons is considerably larger than the lifetime caseload of an individual neurosurgeon even in the largest neurosurgical centers. The Society of British Neurosurgeons, however, “recognizes the national clinical audit as a key approach to improving patient care, outcomes, safety and sees the NNAP as a key driver of this process”.<sup>26</sup> The public reporting of surgeon-specific mortality rates has already lead to a reluctance among surgeons to accept difficult surgical cases in an effort to avoid higher-than-expected mortality statistics.<sup>27,28</sup> Our results question the use of mortality, even if risk-adjusted, as a sole measure of quality of care in cranial neurosurgery.

Regardless of its popularity as a data source for neurosurgical outcome research, the NSQIP database has received no external validation for accuracy and the results of Rolston and coworkers indicate evidence of Current Procedural Terminology code and postoperative diagnosis mismatch in 0.4% to 100.0% of cases.<sup>17</sup> Furthermore, the NSQIP has served for developing a novel preoperative frailty score for predicting 30-d morbidity and mortality after cranial neurosurgery,<sup>29</sup> however, the ACS universal risk calculator based on the same data source is discriminative only for 30-d mortality but not other adverse events in neurosurgical patients.<sup>30</sup> Even though the NSQIP criteria detected a high percentage of patients with major complications in our cohort, limited caseloads in individual hospitals along with the rarity

of outcome events hinders the sensible use of such registries.<sup>31</sup> Furthermore, registries that rely on administrative data with little disease-specificity lack the level of clinical detail required for true quality improvement.<sup>32</sup> Despite the wide contribution and claimed benefits, recent alarming reports have shown no association between participating in NSQIP and improvement in patient outcomes.<sup>33,34</sup>

As the first national prospective registry focusing on outcome and quality of care in neurosurgery, the N<sup>2</sup>QOD holds great expectations for benchmarking and true comparisons between treatment centers. Such prospective multicenter data may be considered more reliable, specialty-specific and clinically relevant than previous retrospective analyses of administrative data.<sup>35</sup> The N<sup>2</sup>QOD employs composite outcome events instead of individual complications, which reduces the sample size requirement for reliable comparisons between treatment centers. The N<sup>2</sup>QOD criteria, however, failed to identify almost a fourth of all patients with postoperative complications reported in our prospective cohort, indicating that the criteria may not be sensitive for minor complications that may still have a great impact on the recovery and postoperative quality of life after major surgery.

Our results highlight that the medical community, policy-makers, and other stakeholders need to be very careful not to assess and quantify the quality of care—a principal measuring tool not only for patient safety but also for financial reimbursement in health care—with unreliable or inadequate instruments. Measuring the quality of care should be based on strong scientific evidence, just like the clinical care we deliver to our patients. To meet the requirements of heavy-handed government regulation and to avoid financial penalties, health care

facilities including neurosurgical centers are forced to participate in multiple overlapping quality programs.<sup>35</sup> The programs fail to adjust for case-specific circumstances, and as a result high-risk patients struggle to find physicians willing to operate due to a punitive component associated with the quality databases.<sup>35,36</sup> Even though complete transparency in outcomes reporting is imperative, it is crucial that public outcomes reporting such as the NNAP surgeon-specific mortality rates or the Centers for Medicare and Medicaid Services Physician Compare website reflect the level of patient health literacy. Furthermore, intercultural differences in healthcare and funding systems hinder the worldwide applicability of quality registers without a careful and thorough validation process.

In the future, instead of institutional or doctor-dependent definitions and reporting of adverse outcome events, patient-centered reporting approaches, such as patient-reported outcomes<sup>24</sup> and patient-reported outcome measures (PROMs),<sup>37,38</sup> are promising options for monitoring quality of care in neurosurgery. To promote patient safety and patient centeredness, the neurosurgical community should strive for a prompt consensus on outcome events and outcomes reporting, including validating neurosurgery-specific PROMs. This would also be a crucial step towards developing a neurosurgery-specific risk-assessment method, which would facilitate benchmarking by enabling corrections for differences in the case-mix between treatment centers.

## CONCLUSION

In order to improve the quality of care and patient safety in major surgeries, such as neurosurgery, mortality, and administrative data have limited value in providing reliable tools for quality of care comparisons and patient safety initiatives. In neurosurgery, despite being driven undoubtedly by the best of intentions, the current quality registers may backfire on the neurosurgical community and on a larger scale the whole medical profession. The physicians need to take the lead in designing reliable and accurate quality measures, interpreting the results and utilizing them to power intelligent changes in health care to truly improve the quality of care.

## Disclosures

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## COMMENT

The authors performed a prospective evaluation of 418 adult patients operated in a neurosurgical center. They compared 3 different neurosurgical quality registries of the US and UK based on the outcome of their patient collective. The failure of all programs to recognize major postoperative complications is an important conclusion of this study, especially since funding is and will be attached to these registries. It is of utmost importance for neurosurgical centers to analyze quality data bases in order to discover limitations and enable improvement. This study could not be timelier, since the implementation of value-based healthcare is a present, ongoing discussion. The definition and expectations of quality as an outcome factor has been thoroughly discussed, how to measure it however, is the biggest challenge.

**Eric Suero Molina**  
Münster, Germany